REMARKS/ARGUMENTS

Claims 1-17 are active. Claims 1 and 3 have been revised to remove a product-by-process limitation and the redundant term "prior to the adding, combining or mixing". Equation (I) refers to discrete values for ingredients (A) and (B) which one would have understood would have been calculated prior to adding, combining or mixing. One of skill in the art would not admix (A) and (B) and then attempt to determine the individual weights of (A) and (B). However, for clarity, this redundant language has now been dropped and the relationship between the content of (A) and (B) remains defined by Equation (1). Claim 2 has been revised to specify that the erythritol is a powder as supported by paragraphs [0019] and [0032]. New claims 14-17 find support on pages 14-18 of the specification. No new matter has been added.

Rejection—35 U.S.C. § 112, first and second paragraphs

Claims 1, 3-6, 8-9 and 12 were rejected under 35 U.S.C. 112, first and second paragraphs, as introducing new matter or as being indefinite with respect to the phrase "prior to the adding, combining, or mixing". This rejection is moot in view of the amendments above which redact this redundant phrase.

Equation (1) referred to by these claims is disclosed on page 10, paragraph [0016] of the specification and requires the selection of particular, specific relative amounts of components (A) and (B). For example, when (B) water content = 15 wt%, then (A) erythritol content can range between 30 and 60 wt.% because: 15 wt.% x 0.3 + 25 = 29.5 wt.% $\leq$ 30-60 wt.%. For a water content at the upper end of the range for (B): 30 wt.% x 0.3 + 25 = 34 $\leq$any value above 34 up to 60 wt.%. Consequently, when read by one of skill in the art in light of the disclosure, this limitation would be definite.

Rejection—35 U.S.C. §103

Claims 1-13 were rejected under 35 U.S.C. §103(a) as obvious in view of the combination of Leusch (WO 00/56276) and DeSadeleer (US 5,973,212). This rejection cannot be sustained because the prior art did not suggest the benefits of selecting the ranges required by claim 1, namely, the ratio of components (A) and (B) specified by Equation (1).

Leusch relates to "treating or preventing the formation of caries" and seeks to allow a non-cariogenic carbohydrate to be absorbed and penetrated into plaque as described on page 2, *Brief Summary of the Invention*, "said polyol is used in a level sufficient to promote greater uptake of said non-cariogenic carbohydrate by plaque". Page 3 of Leusch indicates that non-cariogenic carbohydrate includes ***erythritol***. In order to allow erythritol to be absorbed into plaque Leusch requires that erythritol be dissolved since erythritol in the crystal state or particle state cannot be absorbed into plaque. Consequently, one of ordinary skill in the art would not have sought to include erythritol in an oral composition based on Leusch since it is not completely dissolved and thus would not have been expected to achieve the objective of Leusch which was to promote uptake of non-cariogenic carbohydrate by plaque.

In contrast, the invention "relates to a toothpaste composition excellent in a cooling sensation", specification, page 1, paragraph [0001]. Applicants have demonstrated that when the ingredients are admixed in the proportions required by Equation (I) in claim 1 that an improved cooling sensation results because component (A) erythritol does not completely dissolve in the composition. Undissolved erythritol has a positive heat of solution which means that it absorbs heat endothermically when it dissolves. These superior properties are further described in Tables 1 and 2 from the attached Declaration, which are reproduced below:

Table 1

	Ref.	Ex. 1'	Ex. 2'	Ex. 3'	Ex. A	Comp. Ex. 1	Comp. Ex. 2	Comp. Ex. 3	Com. Ex. 4
Erythritol	—	40	50	60	38	10	17	15	27
Water	20	20	25	18	25	23.5	20	25	25
Xylitol									
Glycerin	14	14	0	0	14	14	14	14	14
Sorbitol	46.99	6.99	5.99	2.99	3.99	33.49	29.99	26.99	14.99
Sodium Carboxymethylcellulose	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
Xanthan gum	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
Saccharin sodium	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
Sodium fluoride	0.21	0.21	0.21	0.21	0.21	0.21	0.21	0.21	0.21
Sodium lauryl sulfate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Abrasive silica	10	10	10	10	10	10	10	10	10
PEG	5	5	5	5	5	5	5	5	5
Flavor	1	1	1	1	1	1	1	1	1
Total amount	100	100	100	100	100	100	100	100	100
Cooling sensation	—	A	A	A	A	D	C	D	B
Conforms to Equation (1)? (see values in Table 2)	No	Yes	Yes	Yes	Yes	No	No	No	No

Table 2

	Water (wt.%)	Erythritol (wt.%)	wt. % of (B) water x 0.3 + 25	Satisfies Equation 1?	Evaluation
Ex. 1	20	40	31	Yes (31 < 40)	A
Ex. 2	25	50	32.5	Yes (32.5 < 50)	A
Ex. 3	18	60	30.4	Yes (30.4 < 60)	A
Comp. Ex. 2	17	20	30.1	No	C
Comp. Ex. 3	25	15	32.5	No	D
Comp. Ex. 1	23.5	10	32.05	No	D
Comp. Ex. 4	25	27	32.5	No	B
Ex. A	25	38	32.5	Yes (32.5 < 38)	A

An evaluation of "A" corresponds to the highest degree of cooling sensation; a value of "D" refers to the lowest where no cooling sensation is obtained. "B" and "C" represent intermediate values as explained in more detail in the attached Declaration. The Declaration shows that a representative number of different compositions conforming to Equation (1) have superior properties, while a representative number of similar compositions that do not

conform to Equation (1) do not. These results are commensurate in scope with the claim language as graphically depicted by the Figure in the Declaration.

There is no reasonable expectation of success for these superior cooling properties in the prior art. As noted above, Leusch seeks to totally dissolve non-cariogenic carbohydrates to facilitate their uptake into plaque and cannot provide a reasonable expectation of success for the cooling effect achieved by the invention when (A) and (B) are combined in a ratio defined by Equation (1).

The prior art does not suggest that selecting a ratio of components (A) erythritol and (B) water in conformance with Equation (1) would provide any benefit. It also fails to teach that selection of a ratio of components (A) and (B) as defined by Equation (1) is a ***results-effective variable*** for obtaining any benefit and thus no argument that it would have been routine to optimize these values can be sustained. As held in *In re Antonie*, 195 USPQ 6, 8-9 (CCPA 1977), there must be evidence in the record that the prior art recognized that particular parameter affected the result. That is lacking here.

As discussed in their prior response, DeSadeleer was relied upon merely for its disclosure of a particle size range for erythritol-containing compositions and fails to suggest a toothpaste containing particulate erythritol. Like the primary reference, it also fails to disclose Equation (1) and the surprising benefits obtained by selecting the amounts of (A) and (B) according to this equation. Consequently, DeSadeleer cannot remedy the deficiencies in the primary reference Leusch. Accordingly, this rejection cannot be sustained.

Provisional Rejection—Obviousness-type Double Patenting

Claims 1-13 have been *provisionally* rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over the claims 1-3 and 6 of U.S. 11/512,326. This provisional rejection cannot be sustained because the copending

application does not suggest selecting a ratio of components (A) and (B) as defined by Equation (1). The copending application has a filing date of 08-30-2006 and the present case was earlier filed on 03-04-2005. Therefore, this provisional rejection may be withdrawn pursuant to MPEP 804(I)(B)(1):

> If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

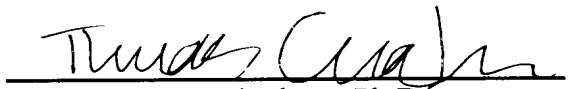
The Applicants submit that the foregoing amendments and remarks address all the remaining rejections and place this application in condition for allowance. Accordingly, this provisional double patenting rejection can no longer be sustained.

Conclusion

In view of the amendments and remarks above, the Applicants respectfully submit that this application is now in condition for allowance. An early notice to that effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Stephen G. Baxter



Thomas M. Cunningham, Ph.D.
Attorney of Record
Reg. No. 45,394

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/07)